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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,494	07/25/2001	Robert Thomas Hudak	17072-002001/0271	6752

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,494

Applicant(s)

HUDAK, ROBERT THOMAS

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/13/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Status of the claims

Applicant's amendment filed December 5, 2005 is acknowledged and has been entered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 74, 75, 79, 85-92, and 94-102 are rejected under 35 U.S.C. 102(e) as being anticipated by Cui et al (US 6,576,193).

Cui et al disclose devices and methods for collecting a fluid specimen and testing the fluid specimen for detecting the presence of a particular analyte. Cui et al disclose a first compartment (chamber) for fluid collection. Cui et al disclose a second compartment (reservoir) for receiving a portion of the fluid. Cui et al disclose a valve interposed between the first compartment and the second compartment (Fig. 1 and Fig. 9). Cui et al disclose that the valve comprises a well (22)(compartment) for holding an aliquot of the specimen. Cui et al disclose that the first compartment (chamber) comprises a lid for sealing the fluid within the first compartment (col. 4, lines 1-9). Cui et al disclose that the second compartment (reservoir) is spaced to allow receipt of a test device such as a test strip (col 5). Cui et al disclose that test strips using immunoassays or chemical patches can be used to determine an analyte of interest (col

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7, lines 37-60). Cui et al disclose that the fluid sample can be blood, plasma, serum or urine (col. 7, lines 1-20). Cui et al disclose actuating the valve to cause a portion of the sample to enter the reservoir and detecting an analyte of interest. Referring to Figure 2, Cui et al disclose the valve 20 comprises a well (valve compartment) in fluid communication with the chamber. One skilled in the art would recognize that when the valve is actuated that the well will be horizontal at the 3:00 o'clock position (second position) (would not be in fluid communication with the chamber or the reservoir) and then proceed to the 6:00 o'clock position in which the well (valve compartment) would be in fluid communication with the reservoir and not the chamber. Cui et al disclose that the analyte can be a protein (col 7) and also discloses that visible indicators are used to detect the analyte (col 7).

With respect to the recitation "the valve being inoperable after a first actuation". This recitation is not given patentable weight because it is intended use of the valve and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Nelson et al (US 5,115,934).

See above for teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the seal is tamper resistant.

Nelson et al disclose a tamper resistant seal for containers. Nelson et al disclose that this tamper resistant seal provides for a cover that is secure but yet may be easily removed providing access to the container.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a tamper resistant seal as taught by Nelson et al into the device and method of Cui et al because Nelson et al shows that this tamper resistant seal provides for a cover that is secure but yet may be easily removed providing access to the container.

6. Claims 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Alley (US 2002/00446614).

See above for the teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the seal comprises at least one O-ring.

Alley discloses a seal comprising an O-ring. Alley discloses that the use of this O-ring provides a means of securing the seal to the container. Furthermore, the use of O-rings in a seal is well known in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an O-ring as taught by Alley into the device of Cui et al because Alley shows that the use of this O-ring provides a means of securing the seal to the container.

7. Claims 80 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Mitsumaki et al (US 4,680,270) and Pampinella (US 2002/0023482).

See above for the teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the valve is a piston valve and a detachable valve handle for actuating the valve.

Mitsumaki et al teaches the equivalence of rotary valves and slide valves in the art (col 2, lines 37-40).

Pampinella teaches a valve assembly (slide valve) comprising a valve plunger within the valve chamber. Pampinella et al teaches a valve handle which is detachably connected to the valve plunger (page 2, paragraph 0034 and Figures 4 & 5).

Pampinella teaches that the use of this valve facilitates the opening and closing of the valve.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a slide valve and handle as taught by Pampinella et al into the device of Cui et al because Mitsumaki et al shows that it is known in the art to use slide valves instead of rotating valves and because Pampinella teaches that the use of this valve facilitates the opening and closing of the valve, therefore a skilled artisan can have a reasonable expectation of success in incorporating a slide valve comprising a valve plunger and a detachable handle such as taught by Pampinella in the device of

8. Claims 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Carter et al (US 4,909,933).

See above for the teachings of Cui et al.

Cui et al differs from the instant invention in failing to specifically teach the valve comprises O-rings.

Carter et al disclose a valve for regulating the flow between multiple chambers. Carter et al disclose the use of O-rings with the valve (col 4, lines 27-45). Carter et al discloses that the use of O-rings ensure a leak-proof arrangement thus minimizing fluid loss.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate O-rings as taught by Carter et al into the valve of Cui et al because Carter et al teaches that the use of O-rings ensure a leak-proof arrangement thus minimizing fluid loss.

9. Claim 93 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Ehrenkranz (US 4,769,215).

See above for the teachings of Cui et al.

Cui et al. differs from the instant invention in failing to teach the chamber comprises an adulteration determination device.

Ehrenkranz discloses a urine collection apparatus, which comprises a thermometer within the device. Ehrenkranz disclose a detector to insure that chemicals haven't been added to the urine to adulterate the specimen (abstract). Ehrenkranz discloses that the use of this thermometer and detector provides a means for determining the freshness of the urine and also provides an alternative for physical examination (col. 5, lines 19-37 and abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a detector and a thermometer as taught by Ehrenkranz into the device of Cui et al because Ehrenkranz shows that the use of this detector and thermometer provides a means for determining the freshness of urine and also provides an alternative for physical examination.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 74-102 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-62 of U.S. Patent No. 10/211,199. Although the conflicting claims are not identical, they are not patentably distinct from each other because one skilled in the art would recognize that the narrow claims of the device concerning the valve in application 10/211,199 would encompass the more broad claims of the device in application 09/915,494 .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant's arguments filed December 5, 2005 have been fully considered but they are not persuasive.

Applicant argues that the Examiner appears to be referring to case law that addresses a mere recitation of use in a preamble of a claim, which is not considered a limiting element if it is not necessary to breath life and meaning into the claim . This is not found persuasive because Examiner is not relying on case law that addresses a mere recitation of use in a preamble of a claim. Nowhere in the office action dated 08/31/05 does Examiner indicate case law. Examiner is stating that Applicant has not recited any structural difference over the prior art. Therefore, Cui et al meets all the limitations of the claim (a chamber, a reservoir, a valve functionally interposed between the chamber and the reservoir and having a compartment for holding an aliquot of specimen and transporting the aliquot from the chamber to the reservoir, the valve having first, second and third positions). The recitation "the valve being inoperable after

a first actuation” is not given patentable weight because it is a recitation of intended use of the valve and as stated above Cui et al disclose the same device and valve as recited. Thus, since Cui et al disclose structurally the same device and valve as recited in the instant claims, it is inherent that the device and valve would be capable of being inoperable after a first actuation.

Applicant argues that the recitation “the valve being inoperable after a first actuation” is not a mere recitation of use but a stated characteristic of the valve. This is not found persuasive because Cui et al discloses the same structural features as recited in the claims and thus it is inherent that the device and valve would possess the same characteristics as currently recited. Applicant further argues that the limitation “the valve being inoperable after a first actuation” must be evaluated in view of the specification, which contains relevant disclosure at p. 21, line 10. This is not found persuasive because although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Cui fails to disclose a valve that is inoperable after a first actuation and that none of the secondary references cited by the Examiner disclose this limitation of the cited claims, nor suggest the use of the valve recited in the claims. Therefore, the cited combinations of art do not disclose all of the claim limitations. This is not found persuasive because as stated above it is the Examiner’s position the Cui reads on the instantly recited claims and thus the Examiner maintains that the

combination of the secondary references with Cui et al is appropriate and reads on the instantly recited claims.

Allowable Subject Matter

12. The following is a statement of reasons for the indication of allowable subject matter: Even though the following limitation is not recited in the claims the following feature would be considered allowable: The allowable feature would be wherein the handle further includes a frangible head which disengages from the valve after the valve is actuated and wherein the valve cannot be actuated with the handle disengaged therefrom.

13. The closest prior reference is considered to be Pampinella (US 2002/0023482). See above for teachings of Pampinella. Pampinella fails to teach or suggest the handle further includes a frangible head, which disengages from the valve after the valve is actuated, and wherein the valve cannot be actuated with the handle disengaged therefrom.

Conclusion

14. No claims are allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
Art Unit 1641
January 9 2006



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01/09/06